

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61N 1/375	A1	(11) International Publication Number: WO 00/50120 (43) International Publication Date: 31 August 2000 (31.08.00)
(21) International Application Number: PCT/SE00/00203 (22) International Filing Date: 1 February 2000 (01.02.00) (30) Priority Data: 9900682-7 25 February 1999 (25.02.99) SE (71) Applicant (for all designated States except US): PACESETTER AB [SE/SE]; S-175 84 Järfälla (SE). (72) Inventor; and (75) Inventor/Applicant (for US only): MAGNUSSON, Gunnar [SE/SE]; Orrfjärdsgränd 7, S-120 51 Årsta (SE). (74) Common Representative: PACESETTER AB; Patent Department, S-175 84 Järfälla (SE).		(81) Designated States: US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: IMPLANTABLE TISSUE STIMULATING DEVICE (57) Abstract <p>A housing (1") for an implantable tissue stimulating device is disclosed. The housing (1") is connectable to an electrode lead (3") having an electrode, which is adapted to be in contact with a tissue, at a distal end thereof. When implanted, the housing (1") is acting as an electrode and shaped so as to create low strength electric fields in regions where unwanted stimulation of muscles can occur.</p> <div data-bbox="820 1129 1404 1396" data-label="Image"> </div>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LJ	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

IMPLANTABLE TISSUE STIMULATING DEVICE**FIELD OF THE INVENTION**

5 The invention relates to a housing for an implantable tissue stimulating device, especially an implantable heart stimulation device.

BACKGROUND OF THE INVENTION AND RELATED ART

10

Heart stimulation devices for human beings, such as pacemakers are usually implanted in the chest, mostly on the left side, a short distance below the clavicle or collar bone. The device will then rest between the pectoralis major and the skin. An electrode lead supplies electric pulses to the heart from the device. The electrode lead includes: one or more electrodes; a connector, at the proximal end of the electrode lead, for connection of the lead to the stimulation device; conductor(s) between the connector pin and the electrode(s) whereof one typically is located at the distal end of the lead; and, insulation. The electrode lead is typically passed upwardly over the clavicle and is connected to the heart through a vein adjacent to the clavicle. Usually, the housing of the heart stimulating device is made of conductive material, and electric pulses to the heart are delivered by means of a distal electrode of the electrode lead, being located in the heart in electrical contact with the tissue. The housing is implanted so as to be in electrical contact with the surrounding tissue, and constitutes a second electrode surface. The object is to create an electrical field at the interface of the distal electrode of the electrode lead (stimulation electrode) with the underlying myocardium. However, in a device as described, an electrical field will also be created between the stimulation electrode and the housing. This may, depending on the strength of the field, cause unwanted stimulation of other muscles subjected to

15

20

25

30

35

the field, e.g. the pectoralis major. To avoid this effect, parts of the housing can be provided with an insulating cover, e.g. of parylene. Usually the whole housing except for a contact window in a central portion of the side of the housing facing the skin, when implanted, is covered with parylene. In such a case the electric field from the housing will be concentrated to the area of the window.

US-A-5 480 416 refers to such devices as prior art, and further discloses a pacemaker having two sides covered with parylene, while an edge joining the two sides is uninsulated, and constitutes a contact surface. Thus this pacemaker can be implanted with either of its two sides facing the skin of its carrier.

In US-A- 5 658 321 there is disclosed an implantable defibrillator or pulse generator having an electrically conductive housing used as an electrode. The exterior surface of the housing is provided with ridges. Hereby the surface area is increased, and the electrical resistance in the housing/tissue interface is decreased. By the arrangement of sharp corners in connection with the ridges, a further resistance reduction is achieved.

A further casing for a power supply and pulsation control circuitry of a cardiac pacer is disclosed in US-A 4 094 321. This casing comprises a substantially flat bottom surface and a shallow dome-shaped top, which tapers down to a thin peripheral edge of a small radius of curvature juxtaposed to the bottom and merging curvilinearly therewith. The substantially flat bottom surface can be of metal, epoxy or other suitable inert coating. Further, said bottom surface is provided with a catheter storage means, including rims or grooves. When implanted the casing is located with the dome-shaped top facing

the skin, and the substantially flat surface supported by muscles or ribs.

5 The method widely used today, for preventing generation of electric fields in regions where they could cause unwanted stimulation of muscles, by covering portions of a housing, which serves as an electrode, with an insulating material such as parylene, is an effective method. However, it is costly due to the step of the application of the parylene itself and the
10 pre-treatment and after treatment steps.

SUMMARY OF THE INVENTION

15 It is an object of the invention to provide a housing for an implantable tissue stimulating device where the electric fields, which are generated around the housing and could cause unwanted muscle stimulation, could be eliminated, or at least reduced to a safe level, where the risk of unwanted muscle stimulation is eliminated, which housing can be produced in a
20 simpler and more cost-effective manufacturing process.

A device according to the features of claim 1 achieves this.

25 By these features, a housing for an implantable tissue stimulating device is provided, where, when implanted, the housing is acting as an electrode and shaped so as create low strength electric fields in regions where unwanted stimulation of muscles can occur, without the need of covering portions of the housing with an insulating layer.

30 By the arrangement of a curved circumferential first wall section connected to a first wall having a generally flat exterior surface, and a curved circumferential second wall section connected to a second wall having a generally flat
35 exterior surface, where the first wall section has smaller

radius of curvature than the second wall section a favourable electric field distribution around the housing is obtained.

Roughening the surface or providing the surface with ridges or irregularities can increase the electrical field at the region of the wall facing the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 schematically shows a pacemaker implanted in a patient.

Figure 2 is a schematic view of a prior art pacemaker.

Figure 3 shows a cross section taken at III-III in FIG 2.

Figure 4 is a schematic view of an embodiment of a housing for an implantable tissue stimulating device according to the invention.

Figure 5 shows a cross section taken at V-V in FIG 4.

Figure 6 is a schematic view of an alternative surface structure of the first wall of the housing of the invention.

Figure 7 shows a cross section taken at VII-VII in FIG 6.

Figure 8 is a schematic view of a further alternative surface structure of the first wall of the housing of the invention.

Figure 9 shows a cross section taken at IX-IX in figure 8.

DESCRIPTION OF PREFERRED EMBODIMENTS

With reference to FIG 1, a conventional placement of a pacemaker implanted in a patient is shown. A housing 1 for a pulse generator is implanted on the left side of the chest. The housing is conductive, made of a bio-compatible material such as titanium, and hermetically sealed against intrusion of body fluids and tissue when implanted. On top of the housing a header 2 is arranged. The header is made of transparent epoxy resin, and is moulded onto the housing. The header includes a female portion of an electrical connector coupled to the circuits of the pulse generator. An electrode lead 3 includes at its proximal end a male connector 31 (connector pin, not shown) for electrical connection with said female connector. At the distal end the electrode lead 3 is provided with a stimulation electrode 32, which is located in the heart in electrical contact with the tissue. A stimulation pulse generated by the pulse generator will be applied between the electrode 32 and the housing 1, which also acts as an electrode. The electrode 32 may also serve as a sensing electrode, and the housing 1 then serves as the second sensing electrode. Between the male connector 31 and the electrode 32 the lead 3 includes an electrically conductive wire provided with insulation.

Alternatively the lead may comprise an additional electrode, preferably also located in the heart. In such a case, the sensing is preferably performed by means of the electrodes of the lead, and the number of insulated wires of the lead will be the same as the number of the electrodes.

In FIG. 2, the housing and a proximal lead portion, of a prior art device to be implanted as shown in FIG 1, is shown in an enlarged view. The housing 1' has a first wall 11' having a first generally flat exterior surface. The housing is adapted to be implanted with this first surface facing the skin of the patient.

FIG. 3 is a cross section taken at III-III in FIG. 2, with the housed parts and components omitted, for simplicity. Opposed to the first wall 11', a second wall 12' having a second generally flat exterior surface, is provided. The first and second walls 11', 12' are joined by a connecting wall, and corners 18' are formed where the connecting wall joins the first wall 11' and the second wall 12', respectively. When a voltage is applied between the electrode of the lead and the housing, an electric field will be generated around the housing. This is illustrated with schematic field lines. Along the corners 18' the field will exhibit strong field concentrations, leading to high current densities in the surrounding tissue and possibly to unwanted stimulation of muscles. To prevent this, prior art devices have been provided with an insulating parylene coating of the whole housing except for a central portion of the surface facing the skin of the patient, as mentioned above. This portion or window 19' is shown with broken lines in FIG. 2.

An embodiment of a housing for an implantable tissue stimulating device according to the invention is shown in FIG. 4, and a cross section taken at V-V thereof is shown in FIG. 5. This device is also adapted to be implanted as shown in FIG. 1. Also in FIG. 5 the housed parts and components are omitted, for simplicity. A housing 1" comprises a first wall 11", having a first generally flat exterior surface, and a second wall 12" having a second generally flat exterior surface. The first and second walls 11", 12" are joined by a third circumferential wall 13". The third wall 13" comprises a curved circumferential first wall section 14" that is connected to the first wall 11" around its periphery. The third wall 13" further comprises a

curved circumferential second wall section 15" that is connected to the second wall 12".

On top of the housing 1" a header 2" is provided. It is of the above mentioned kind, made of transparent epoxy, and moulded onto the housing 1". The header 2" could be moulded to the housing 1" so as to cover an adjacent portion of the second wall section 15" and possibly also an adjacent portion of the first wall section 14".

The first 11", second 12" and third 13" walls are all made of an electrically conductive material, such as titanium, and the housing is hermetically sealed.

As seen in FIG. 5 the radii of curvature of the first wall section 14" and the second wall section 15", taken in a plane perpendicular to the first 11" and second 12" walls are different. The first wall section 14" has a smaller radius of curvature, whereas the second wall section 15" has a greater radius of curvature. The ratio between the curve radii is in the range of 1:2-1:6, and preferably around 1:4. When discussing the radii of curvature of the wall sections, it is assumed that the thicknesses of the wall sections are uniform. However, this is not necessary, and in cases where a curve radius of a wall section is difficult to define it is referred to the exterior surface of the actual wall section.

The condition that the first wall section 14" has smaller radius of curvature than the second wall section 15" is generally valid for all planes through and perpendicular to the first and second walls 11", 12". Preferably the ratio between the radii of curvature is the same all the way along the third wall 13". However, in the region of the header, the desired

effect could be obtained due to the insulating properties of the header material, especially when the header covers a portion of the second wall section 15". In such a case the relation between the radii of curvature at this location can be somewhat different than mentioned above, without departing from the spirit of the invention.

The first and second wall sections 14", 15" are circularly curved in said planes. For a housing shown in FIG. 5, having a thickness of e.g. about 6 mm, i.e. the distance between the exterior surfaces of the first and second walls, the radii of curvature could be 1 mm and 4 mm for the first and second wall sections 14", 15", respectively. However, the wall sections may be curved in other shapes, e.g. partially elliptical. What's important is that the curve of the first wall section 14" is sharper than the curve of the second wall section 15". For housing thicknesses of e.g. 8 and 9 mm, the radii of curvature could be the same as for the 6 mm case. Practically the smallest radius of curvature (of the first wall section 14") should not be smaller than about 1 mm, even if it could be a sharp corner.

The housing shown in FIGS. 4 and 5 is adapted to be implanted in a patient with the first wall 11" facing the skin. When in use, and when pulses are applied to the stimulation electrode(s) of the electrode lead, an electric field is generated around the housing 1", which is coupled to the pulse generator, and acts as an electrode. By the arrangement of the curved circumferential first wall section 14" and the curved circumferential second wall section 15" where the first wall section 14" has smaller radius of curvature than the second wall section 15" a favourable electric field distribution around the housing is obtained. As illustrated in FIG.5 with

schematic field lines, there will be a lower field concentration in the region around the more smoothly curved second wall section 15" than in the region around the more sharply curved first wall section 14". Due to the weak electric field in the region around the curved second wall section 15" the current density here will be low, and the risk of unwanted stimulation is eliminated or at least heavily reduced. In the region around the curved first wall section 14", on the other hand, the electric field will be relatively strong, resulting in a relatively high current density in the adjacent tissue. This is advantageous since in this region there are no muscles that could be stimulated, and the currents can be distributed in a favourable way.

In order to smoothen the exterior surfaces of the second wall and second wall section, they can be polished. Hereby, small field concentrating irregularities of the surfaces are removed. This will even out the field, and possibly also reduce it. For the exterior surface of the first wall and possibly also for the first wall section the contrary is desired. Therefore the generally flat exterior surface of the first wall and possibly also the first wall section could be blasted in order to achieve a relatively rough surface. Besides a concentration of a field, a decreased electrical resistance in the housing/tissue interface around this wall and wall section is also achieved. Grinding, abrading, brushing, or chemically etching the surface e.g. to generate sharp peaks, which may be elongated ridges, could also form the roughness or irregularities of the surface(s) or individual pointed peaks.

FIG 6 shows the exterior surface of the first wall 11" being roughened, textured or contoured. The exterior surface of the first wall 11" is provided with an array of grooves 17". The grooves 17" alternate with an array of ridges 16", each of

which stands between and defines adjacent grooves. The grooves can be formed as mentioned above or by cutting, milling, or stamping. As an example, the grooves can be cut to a depth of 0.25 mm and a width of 0.40 mm, while the ridges have a width of 0.40 mm.

In FIG 7 a cross section taken at VII-VII in FIG 6, is shown. Here, the ridges 16" and grooves 17" are shown somewhat enlarged. The ridges are shown to be rectangular in cross section. However they could have V-shaped cross-section.

FIG 8 shows an alternative shape of the grooves 17" and ridges 16". Here they are formed in an annular and concentric pattern. Other patterns are also possible, e.g. elliptic or spiral. In Fig 9 a cross section taken at IX-IX in figure 8, is shown. Also here, the ridges 16" and grooves 17" are shown somewhat enlarged. The cross-sectional shapes of the grooves and ridges could be the same as in the embodiment of FIGS 6 and 7.

In the embodiments of the invention above, the first 11", second 12" and third 13" walls are all made of an electrically conductive material that is to be in contact with surrounding tissue. However the third wall 13" could be made of an electrically conductive material, and the second wall 12" and possibly also the first wall 11" made of a non-conductive material, or alternatively covered with an insulating layer.

The curve radii of the irregularities or ridges are very small, at least smaller than 1 mm, and they could be as small as 0.1 mm, or smaller.

Although the invention is described by means of the above examples, naturally, many variations are possible within the scope of the invention.

CLAIMS

1. A housing (1") for an implantable tissue stimulating device, comprising:

- 5 - a first wall (11") having a first generally flat exterior surface,
- a second wall (12") having a second generally flat exterior surface, and
- 10 - a third circumferential wall (13") joining said first (11") and second (12") wall and comprising a curved circumferential first wall section (14") being connected to said first wall (11"), a curved circumferential second wall section (15") being connected to said second wall (12"),
- 15 said housing (1") being connectable to an electrode lead (3") having an electrode, which is adapted to be in contact with a tissue, at a distal end thereof, characterised in
 - 20 - the first wall (11") being adapted to face the skin of a patient,
 - at least the third wall (13") being made of a conductive material, said conductive material being adapted to be in electrical contact with a surrounding tissue and to serve as an electrode, and
 - 25 - a curve radius of the first wall section (14") being smaller than a curve radius of the second wall section (15"), for curve radii in planes essentially perpendicular to the first and second surfaces, whereby
 - when a voltage is applied between the housing (1") and
 - 30 the electrode an electric field is obtained having lower field strength along the curved second wall section (15") than along the curved first wall section (14").

2. The device according to claim 1, wherein

- the first wall (11") being made of a conductive material, and adapted to be in electrical contact with a surrounding tissue and to serve as an electrode conjointly with the third wall (13").

3. The device according to claim 1 or 2, wherein

- the second wall (12") being made of a conductive material, and adapted to be in electrical contact with a surrounding tissue and to serve as an electrode conjointly with at least the third wall (13").

4. The device according to any preceding claim, wherein

- the first (14") and second (15") wall sections being circularly curved in said planes.

5. The device according to claim 4, wherein

- each of the first (14") and second (15") wall sections have centres of curvature along a continuous first and second curve, respectively.

6. The device according to claim 5, wherein

- the continuous first and second curves are essentially parallel.

7. The device according to any preceding claim, wherein

- the ratio between the curve radii is in the range of 1:2-1:6.

8. The device according to any preceding claim, wherein

- the ratio between the curve radii is about 1:4.

9. The device according to any preceding claim, wherein

- the first exterior surface is rough.

10. The device according to any preceding claim, wherein
- the first exterior surface is contoured.

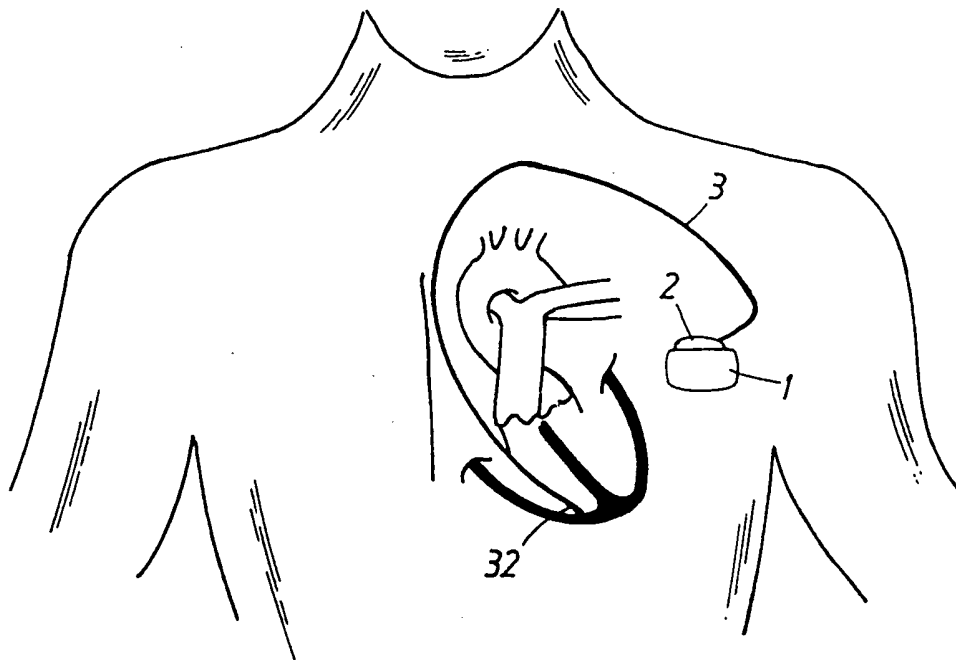
5 11. The device according to claim 10, wherein
- the first exterior surface is provided with a plurality
of ridges (16").

10 12. The device according to claim 11, wherein
- each of the ridges (16") is provided with at least one
edge being a sharp corner.

13. The device according to any preceding claim, wherein
- the second exterior surface is polished.

1 / 3

Fig. 1



2 / 3

Fig. 2

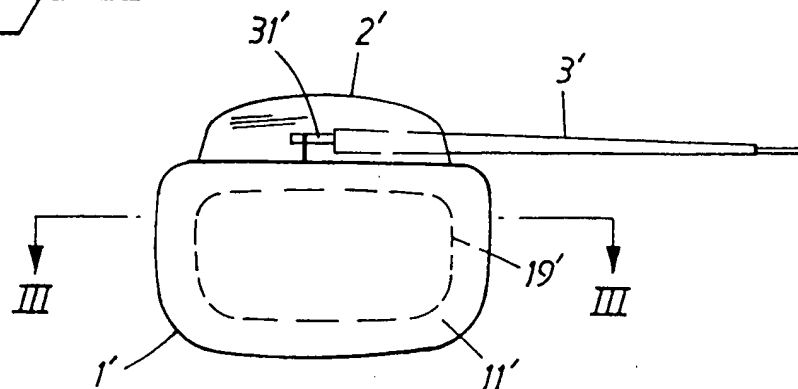


Fig. 3

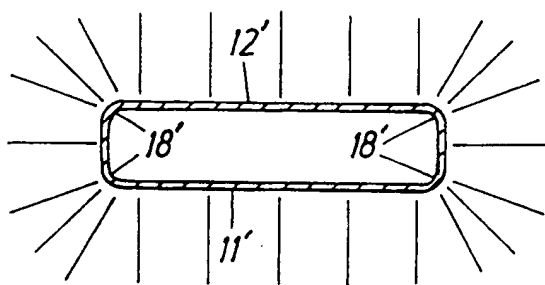


Fig. 4

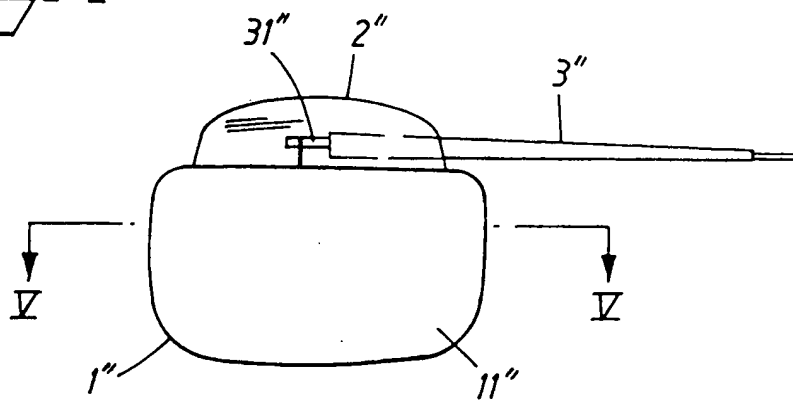


Fig. 5

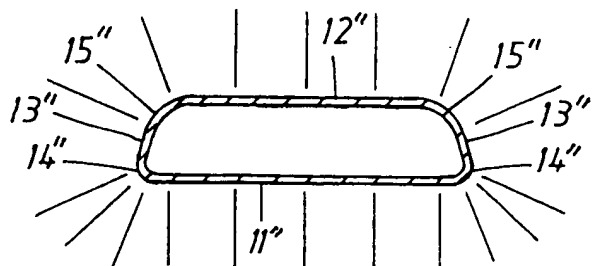


Fig. 6

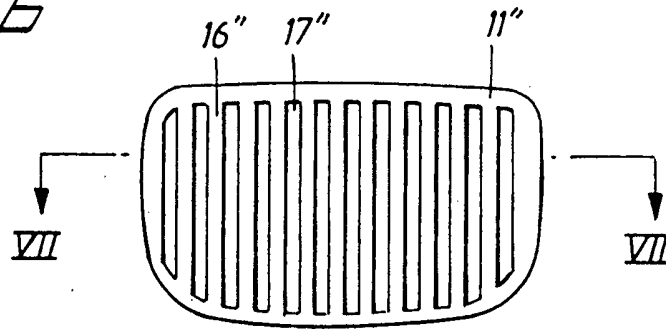


Fig. 7

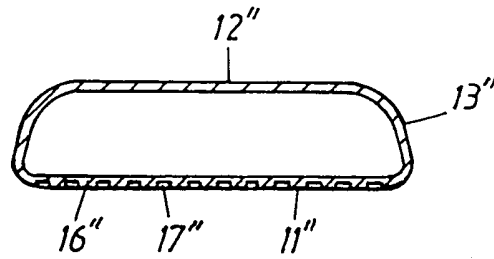


Fig. 8

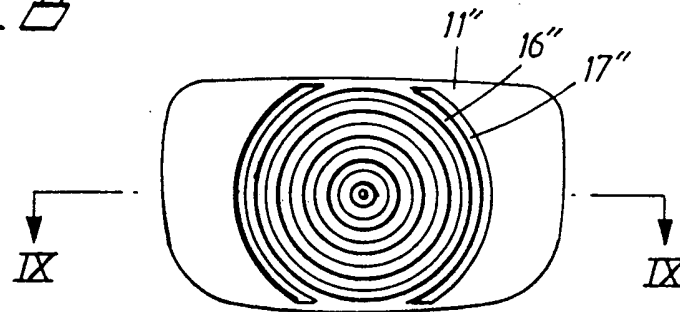
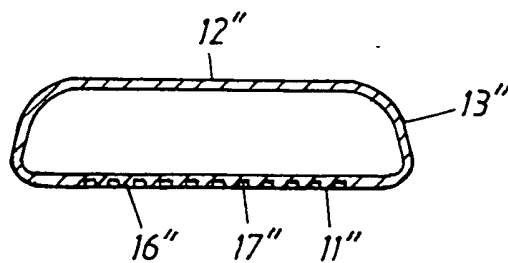


Fig. 9



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/00203

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/375

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3971388 A (DAVID J. COWDERY), 27 July 1976 (27.07.76), column 1, line 32 - line 50, abstract --	1-13
A	US 4071032 A (JOSEPH H. SCHULMAN), 31 January 1978 (31.01.78), column 2, line 13 - line 21, abstract --	1-13
A	US 5476496 A (HANS STRANDBERG ET AL), 19 December 1995 (19.12.95), column 1, line 33 - line 53, abstract --	1-13

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

5 June 2000

Date of mailing of the international search report

26 June 2000 (26.06.00)

Name and mailing address of the ISA/

Swedish Patent Office

Box 5055, S-102 42 STOCKHOLM

Facsimile No. +46 8 666 02 86

Authorized officer

NIKOLAJ HAUTAVIITA/EE

Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/00203

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5662692 A (PAUL M. PASPA ET AL), 2 Sept 1997 (02.09.97), column 4, line 20 - line 30, abstract --	1-13
D,A	US 4094321 A (RUDOLPH MUTO), 13 June 1978 (13.06.78), abstract --	1-13
D,A	US 5480416 A (JOHN GARCIA ET AL), 2 January 1996 (02.01.96), abstract --	1-13
D,A	US 5658321 A (TIMOTHY A. FAYRAM ET AL), 19 August 1997 (19.08.97), abstract -- -----	1-13

INTERNATIONAL SEARCH REPORT
Information on patent family members

02/12/99

International application No.

PCT/SE 00/00203

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3971388 A	27/07/76	JP 1216503 C JP 51078088 A JP 58041070 B	17/07/84 07/07/76 09/09/83
US 4071032 A	31/01/78	CA 1097744 A DE 2703628 A,C FR 2357237 A,B IT 1077901 B JP 1347720 C JP 52113084 A JP 61012702 B	17/03/81 04/08/77 03/02/78 04/05/85 13/11/86 21/09/77 09/04/86
US 5476496 A	19/12/95	NONE	
US 5662692 A	02/09/97	US 5534019 A	09/07/96
US 4094321 A	13/06/78	NONE	
US 5480416 A	02/01/96	EP 0730480 A JP 9509872 T WO 9609087 A	11/09/96 07/10/97 28/03/96
US 5658321 A	19/08/97	NONE	

THIS PAGE BLANK (USPTO)